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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/921,922	08/06/2001	Linda Trolinder	58764.000033	8576

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EXAMINER	
KRUSE, DAVID H	
ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 05/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary	Application No. 09/921,922	Applicant(s) TROLINDER ET AL.	
	Examiner David H Kruse	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *6-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 20-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 August 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group 1, claims 1-5 and 20-27, in Paper No. 8, filed 21 February 2003, is acknowledged. The traversal is on the ground(s) that all of the methods are based on the use of at least one primer or prove which specifically recognizes the 5' flanking region of SEQ ID NO: 3 or the 3' flanking region of SEQ ID NO: 4. In addition Applicant argues that use of a kit according to the claims in a discriminating PCR protocol only detects the EE-GH1 elite event amongst the different cotton leaf plant form a plant comprising different transgenic events. This is not found persuasive because the primer of SEQ ID NO: 3 is directed to the CaMV 35S promoter region of Elite event EE-GH1 and thus would identify any elite event comprising said promoter, in addition the method of Group II is directed to a method of identifying and not to a method of making and thus is directed to a distinct invention.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 6-19 are withdrawn from further consideration pursuant to 37 CFR § 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.

3. This application contains claims 6-19 drawn to an invention nonelected with traverse in Paper No. 8. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR § 1.144) See MPEP § 821.01.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17(i).

Information Disclosure Statement

5. The information disclosure statement filed 15 January 2002 has been considered, a signed copy is attached hereto.

Claim Objections

6. Claims 1, 22, 24, 26 and 27 are objected to because of the following informalities:

At claims 1 and 27, the phrase "event EE-GH1" should read -- elite event EE-GH1 -- for consistency throughout the claims.

At claim 22, the phrase "or plant material thereof" appears redundant and unnecessary, because the claim already recites plant, cell or tissue.

At claim 24, the phrase "a transgenic cotton plant or cell or tissue of a cotton plant" is confusing and the second recitation of "cotton plant" is redundant. The phrase -- a transgenic cotton plant, cell or tissue -- is suggested. See claim 23.

At claim 26, the phrase "The plant or cell or tissue of a cotton plant obtained" should read -- The transgenic cotton plant, cell or tissue produced --, because claim 24

and 25 are directed to a process and claim 26 is directed to a product-by-process, wherein the process is recited in the claim upon which claim 26 depends.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-5 and 20-27 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a cotton plant grown from the cotton deposited at the ATCC under Accession number PTA-3343 comprising Elite event EE-GH1, and progeny of said cotton plant comprising Elite event EE-GH1, does not reasonably provide enablement for any cotton plant that comprises Elite event EE-GH1 not produced from said deposited cotton plant or for a method of making any cotton plant that comprises Elite event EE-GH1 or any transgenic cotton plant, seed, cell or tissue comprising a transgene integrated into the chromosomal DNA region of elite event EE-GH1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant claims a cotton plant or seed comprising elite event EE-GH1 not specifically produced form the cotton plant deposited at the ATCC under Accession number PTA-3343 comprising Elite event EE-GH1, and a process of making said cotton plant. Applicant claims a transgenic cotton plants, seeds, cells or tissues comprising a

transgene integrated into the chromosomal DAN in a region which comprises at least 40 bp which hybridizes under stringent conditions with a sequence which is complementary to the sequence of SEQ ID NO: 5 (the chromosomal DNA regions occupied by elite event EE-GH1) and a process for producing same. Applicant additionally claims seed deposited at the ATCC under Accession Number PTA-3343.

Applicant teaches the Elite event EE-GH1 cotton plant deposited at the ATCC under Accession number PTA-3343 (page 36, 4th paragraph of the specification). Applicant also teaches how Elite event EE-GH1 was made and characterizes the insertion region of the 35S-*bar* transgene in said Elite event (pages 23-30 of the specification).

Applicant does not teach how to predictably reproduce Elite event EE-GH1 in another cotton plant without using the cotton plant deposited at the ATCC under Accession number PTA-3343.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Applicant has only provided guidance to how to predictably make a cotton plant comprising Elite event EE-GH1 by using a cotton plant grown from the deposited seed.

The nature of the art for making a specific elite event in a plant is not predictable because processes directed to insert nucleic acids by homologous recombination in plants is unpredictable. The art teaches that in plants it is difficult to target transgenes to specific loci in the chromosomes and thereby create a heteroallelic recombination target. The art teaches that gene targeting is not an applicable technique for flowering plants, such as cotton in the instant case, given the state of the art at the time of Applicant's invention (see Puchta *et al* 1996, Trends in Plant Science 1(10):340-348, especially pages 340 and 347). The limitation "event EE-GH1" itself limits the enablement of the instant claims to a plant grown from the deposited seed and progeny thereof comprising said "event EE-GH1" because said "event" encompasses the transformation vector DNA that is incorporated into the transformed cotton plant, and the absence of any deleted DNA that came about with said "event". Hence, given the limited guidance by Applicant, the nature of the invention and the unpredictability of the art in producing elite events in plant, it would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention to reproduce Elite even EE-GH1 in another cotton plant.

In addition at claim 20, the invention appears to employ novel plants. Since the plant is essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the plant is not so obtainable or available, the requirements of 35 USC § 112 may be satisfied by a deposit of the plant. A deposit of 2500 seeds of each of the claimed embodiments is considered sufficient to ensure public availability. The specification does not disclose a

repeatable process to obtain the plant and it is not apparent if the plant is readily available to the public. It is noted that applicants have deposited the plant but there is no indication in the specification as to public availability.

(a) If the deposit was made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of the patent., would satisfy the deposit requirement made herein (see 37 CFR § 1.808).

(b) If the deposit was not made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

(i) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(ii) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(iii) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;

(iv) a test of the viability of the biological material at the time of deposit (see 37 CFR § 1.807); and,

(v) the deposit will be replaced if it should ever become inviable.

9. Claims 4, 5, 26 and 27 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At claims 4 and 5 it is unclear if the claimed cotton plant, or seed, cells or tissues thereof comprise Elite event EE-GH1, or Applicant intends to claim non-transgenic cotton plants. Hence, it is unclear what the metes and bounds of the claimed invention are.

Claim 26 is indefinite because it is unclear if "The plant or cell or tissue" is directed to an untransformed plant or cell or tissue, or if it is directed to the regenerated cotton plant comprising the transformed cotton cell or tissue, hence it is unclear what the metes and bounds of the claimed invention are.

Claim 27(ii) is indefinite because the claim reads on a transgenic cotton plant that does not comprise event EE-GH1, said event having a specific meaning, hence a nucleic acid sequence that hybridizes to the complement of the *bar* gene under stringent conditions does not state the metes and bounds of event EE-GH1.

Conclusion

10. Claims 1-5 and 20-27 are free of the prior art, which neither teaches nor fairly suggests a cotton plant comprising Elite event EE-GH1.

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

David H. Kruse
AU 1638

David H. Kruse, Ph.D.
30 April 2003